

## Appendix B UK Research Strategy: Developing the Evidence Base

### 1. Overview

Concurrent to the Phase One pilot implementation, we articulated a research strategy to establish a UK evidence base that complements ongoing research in the United States. The research strategy comprises three sequential phases (see Table 1).

Clinicians and policy makers need confidence that the Serious Illness Care Programme UK has an evidence base that demonstrates impact on care and supports implementation. Accordingly, the phased research strategy began with a research-guided adaptation of the Serious Illness Conversation Guide for use in the UK, and is developing pilot evidence of the feasibility and sustainability of Programme implementation.

Complex interventions have several interacting components requiring careful attention during development, implementation and evaluation.<sup>1</sup> The Serious Illness Care Programme UK can be defined as a complex intervention because of the sensitive nature of the conversation and the unique ‘systems based’ approach to embedding the Programme into practice. We therefore envision future phases to be developed in accordance with the Medical Research Council (MRC) guidance on developing a complex intervention.

### 2. Strategic Objective

To create an evidence base for the Serious Illness Care Programme UK which

demonstrates benefit to patients and their families, we designed a three phase research strategy.

### 3. Phases of Research Strategy

#### 3.1. Phase One: Pre-Pilot Implementation (completed March – September 2016)

##### Research Aim and Objectives

To establish ‘face validity’ of the Serious Illness Conversation Guide (the Guide), assessing applicability and relevance for use within the UK health care setting. The specific objectives of this study were:

- To use a Nominal Group Technique to assess the ‘face validity’ of the Guide with clinicians
- To use a Cognitive Interview Technique to assess the ‘face validity’ of the Guide with patient and public representatives
- To establish consensus on the UK Guide via stakeholder review: -
  - Understand how respondents perceive and interpret the questions in the Guide
  - Identify potential issues with the Guide, such as; appropriateness of the format, language and question wording

This phase has now been completed and resulted in the amendment of the Guide for use in the UK. The Guide was implemented as part of the pilot of the Serious Illness Care Programme UK, and evaluated within The Clatterbridge Cancer Centre during a Feasibility Study (Phase Two of the research strategy).

### 3.2. Phase Two: Pilot Implementation (Sep 2016 – Ongoing 2017/2018)

#### Research Aim and Objectives

To assess the feasibility of the Serious Illness Care Programme UK when implemented within The Clatterbridge Cancer Centre. The specific objectives of the study are:

- To establish the feasibility of the research design to collect meaningful data on the implementation and experience of the UK Programme:-
  - Assess the proportion of patients identified as eligible for serious illness conversations that are recruited to the research
  - Use data collected to illustrate any indicative improvements in communication and patient outcomes
- To conduct qualitative interviews with patients and clinicians to explore their perceptions of engaging in the serious illness conversation using the Guide.

The feasibility study is ongoing. Preliminary findings indicate that it is possible to collect meaningful data on the implementation and experience of the UK Programme. Patients overwhelmingly value the individual care and attention that the conversation facilitates. Interim results are available in Appendix J. Further data collection and analysis will enable a fuller understanding of how the UK Programme works in practice, and will inform the design of future studies in Phase Three of the research strategy.

### 3.3. Phase Three: Post Pilot Implementation Cluster Randomised Controlled Trial of the Serious Illness Care Programme UK

#### Research Aim and Objectives

A Cluster Randomised Controlled Trial (RCT) to assess the effect of the Serious Illness Care Programme UK on patient outcomes. Studies currently in application:-

- In collaboration with the MRC North West Hub for Trials Methodology Research (NWHMTR), a study model and methodology has been developed to generate evidence with which to examine the impact of the Serious Illness Care Programme UK. Applications will be submitted to portfolio eligible national peer reviewed funding schemes – e.g. NIHR, MRC.
- Pilot study in the renal service within the Royal Liverpool and Broadgreen University Hospitals NHS Trust (RLBUHT), to develop the evidence base for patients with serious illness other than cancer.

#### References

1. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 2008; **337**. doi: 0.1136/bmj.a1655.

**Table 1 Research Strategy to Establish the Evidence Base for the Serious Illness Care Programme UK.**

Strategy Milestones	Research
<p><b>1. Pre-pilot implementation (completed Mar – Sep 2016)</b></p>	<p>Assessment of the ‘face validity’, applicability and relevance of the Serious Illness Conversation Guide for use within the UK health care setting.</p>
<p><b>2. Pilot implementation (Sep 2016 – June 2017)</b></p>	<p>Feasibility study of the Serious Illness Care Programme UK, within The Clatterbridge Cancer Centre.</p>
<p><b>3. Post-Pilot Implementation (2018)</b></p>	<p>1. Applications for portfolio eligible peer reviewed funding            - Submission for NIHR-Health Technology Assessment funding for a national Cluster Randomised Controlled Trial across 10 cancer centres in the UK (collaboration with MRC North West Hub for Trials Methodology Research).            2. Protocol to trial the UK Programme within Renal services in the Royal Liverpool University Hospitals NHS Trust (RLBUHT); 2018</p>